KOREAN EMBASSY

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WASHINGTON, D.C. 20008

Facsimile Service Cover Sheet

Date : June 15, 2004	Number of Pages : 2 (Incl. this cover sheet)
TO : FDA Office	Facsimile No. : 301-827-6870 Telephone No. :
FROM : Young Hak Yoo Health & Welfare Counselor	Facsimile No. : (202) 387-0402 Telephone No. : (202) 939-6487
Re : Korean Government's Comments and Questions (Docket No. 2002N-0085)	

Message

Dear Sir/Madam,

My name is Young Hak Yoo, Counselor for Health and Welare, Embassy of the Republic of Korea.

Enclosed please find the Korean government's Comments and Questions on the FDA regulation, "Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food" (Docket No. 2002N-0085), which was announced on April 26.

It would be much appreciated if you could provide us with the answers to our government's Comments and Questions at your earliest convenience.

Thank you very much.

Sincerely yours,

Young Hak Yoo

Young Hak Yoo

Enclosure : As stated

2004N-0184

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Comments and Questions by the KFDA

- The KFDA (Korean Food and Drug Administration) is interested in using the Proposed Rule issued on April 26, 2004 as a reference for Korea.
  - In particular, we think the sampling method can serve as a good reference for us in managing our own sampling regime.

- Regarding the sampling services provision in part C. *Proposed Subpart C operations,* which describes only six general requirements, the KFDA is of the view that the provision is too general to give a full and detailed explanation on sampling operations.
  - Therefore, please let us know if the proposed six general requirements are detailed enough for successful implementation of the proposed sampling method, or if the FDA will require a private laboratory to set more detailed rules on the sampling method, or if the FDA itself will make a detailed guideline for the sampling method.

- We also request the FDA to inform us of the various sampling methods that were explored in preparing the sampling methods of the Proposed Rule, and if possible, that the FDA send us a copy of the various sampling methods explored.

- It is our understanding that the provision *D. Proposed Subpart D-Requirement for Private Laboratories* omits the laboratory accreditation requirement. Please let us know if private laboratories will be required to receive certification such as accreditation by the FDA or whether the FDA will mandate private laboratories to register with the FDA. /End/